No. 09-1175

SUPREME COURT, U.S.
MAY 28 2010
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC., and LOUISIANA WHOLESALE DRUG CO., INC., on behalf of themselves and all others similarly situated,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

When Congress fashioned a court of appeals to adjudicate patent claims, it never intended to abrogate the traditional role of regional circuits to hear appeals in other cases, including antitrust cases. Jurisdiction for the U.S. Court of Appeals for the Federal Circuit was thus limited to cases in which a claim "arises under" federal patent law. In *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), this Court held that if a plaintiffs' claims do not necessarily rely on patent law and can be supported by even a single non-patent theory instead, Federal Circuit jurisdiction is unavailable, and the regional circuit must hear the appeal. This Court also held that the mere presence of patent issues within a case would not suffice to afford the Federal Circuit jurisdiction.

The question presented is whether the Federal Circuit has jurisdiction for an appeal where the well-pleaded complaint stated a single claim for violation of the antitrust laws and sought relief under Section 4 of the Clayton Act, 15 U.S.C. § 15, and where the plaintiff's right to such relief does *not* necessarily depend on the resolution of a substantial question of federal patent law.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Respondents Meijer, Inc. and Meijer Distribution, Inc. hereby certify that Respondent Meijer, Inc. (a private non-governmental entity) is a privately held corporation, which is a wholly-owned subsidiary of Meijer Companies, Ltd.; Respondent Meijer Distribution, Inc. (a private non-governmental entity) is a privately held corporation, which is a wholly-owned subsidiary of Meijer, Inc.; and no publicly held corporation owns 10% or more of the stock of Meijer Inc. or Meijer Distribution, Inc.

Respondent Rochester Drug Co-Operative, Inc. certifies that Rochester Drug Co-Operative, Inc. has no corporate parents and no publicly held corporation holds 10% or more of its stock.

Respondent Louisiana Wholesale Drug Company, Inc. certifies that Louisiana Wholesale Drug Company, Inc. has no corporate parents, and no publicly held corporation holds 10% or more of its stock.

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COUNTER-STATEMENT OF THE CASE

"Federal courts are courts of limited jurisdiction,"[1] and the Federal Circuit's jurisdiction is more limited still. In *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), the Supreme Court imported the test for cases "arising under" federal law[2] to aid in defining the ambit of cases that could be heard by the Federal Circuit. Thus, the Federal Circuit was limited to appeals only in cases where patent law is necessary for a plaintiff to make out a right to relief. If a plaintiff asserts even one alternate non-patent theory supporting its claims, the case may not be heard by the Federal Circuit, even if issues of patent law are present.

The decision by the Second Circuit refusing to transfer this antitrust case to the Federal Circuit holds true to *Christianson*. Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-operative, Inc., and Louisiana Wholesale Drug Co., Inc. ("Plaintiffs") are drug wholesalers and retailers who directly purchased the brand name prescription drug DDAVP (desmopressin acetate) from Defendants Ferring, B.V., Ferring Pharmaceuticals, Inc. ("Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis").[3] Plaintiffs brought a single claim: for

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[1] *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994).

[2] *See* 28 U.S.C. § 1331.

[3] This term shall also refer to Aventis's corporate predecessors.

monopolization under the Sherman Act, 15 U.S.C. § 2. Petitioners' Appendix ("App.") 104a-107a. As set forth in Plaintiffs' Complaint,[4] Defendants engaged in a multi-faceted scheme to unlawfully maintain their monopoly over desmopressin acetate. Defendants' actions included filing a sham citizen petition with the FDA to delay regulatory approval for a prospective generic rival, causing direct purchasers to be overcharged.

In keeping with *Christianson*, the Second Circuit declined transfer. Because the sham citizen petition theory alone, if proven, would sustain a successful claim for monopolization and entitle Plaintiffs to relief without invoking patent law, the Federal Circuit lacks jurisdiction.[5]

Defendants claim that the Second Circuit, rather than follow *Christianson*, should have concentrated on sections of the Complaint which touch on patent issues and surrendered the case to the Federal Circuit. The Complaint does allege that Defendants employed *additional* anticompetitive means to block rivals, including defrauding the United States Patent and Trademark Office ("PTO")

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[4] Consolidated Amended Class Action Complaint, March 31, 2006 ("Complaint"), *reprinted in* Petitioners' Appendix at 58a-116a ("App.").

[5] Defendants do not dispute that monopolization via a sham citizen petition does not rely upon patent law.

to obtain patent no. 5,407,398 ("the '398 patent");[6] making a fraudulent listing in the "Orange Book" maintained by the Food and Drug Administration ("FDA"); and engaging in sham litigation. Defendants harp on these additional allegations to convert a claim that *touches on* patent law theories into a claim that *arises under* patent law.

However, as the Second Circuit observed, *Christianson* focuses on "claims, not theories," App. 15a (quoting *Christianson*, 486 U.S. at 811), and the presence of these additional, alternative theories for relief does not alter the analysis. *See Christianson*, 486 U.S. at 812 (Federal Circuit lacks jurisdiction where plaintiff's "well-pleaded complaint" states "reasons completely unrelated to the provisions and purposes of federal patent law why [plaintiffs] may or may not be entitled to the relief they seek under their monopolization claim.") (citations, internal quotes and original alterations omitted). If Plaintiffs were to succeed on their sham citizen petition theory, both Defendants could be held liable for treble damages under the antitrust laws – and no issue of patent law would need to be addressed or resolved.[7]

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[6] *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

[7] Defendants also propose a new rule – that a plaintiff must show entitlement to "all" relief it seeks without relying on patent law, but this standard finds support neither in *Christianson* nor Defendants' other citations.

Therefore, the Second Circuit "not only may, but must"[8] retain jurisdiction.

Defendants also attempt to manufacture a circuit split, but they cite cases far removed from the one at bar. Indeed, a proper reading of those cases shows they accord with those of the Second Circuit.

Nor is the Federal Circuit's guidance needed here. Defendants have already been to the Federal Circuit once, and it has already held that the only patent potentially at issue here was unenforceable and found evidence that Defendants "*deliberately concealed*" "*pivotal*" information from the PTO. *Ferring, B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1189, 1193 (Fed. Cir. 2006) ("*Ferring II*").

Moreover, although Defendants discuss the question of whether direct purchasers should have standing to bring an antitrust claim, they have not sought certiorari on that point. Regardless, *antitrust standing* is quintessentially a question of *antitrust* law, which regional circuits are competent to address and for which Federal Circuit guidance is unnecessary.

For these reasons, the petition for certiorari should be denied.

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[8] *Pratt v. Paris Gas Light & Coke Co.*, 168 U.S. 255, 260 (1897).

FACTUAL BACKGROUND

I. Regulatory Overview

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et. seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, *codified at* 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establish procedures for obtaining approval to market pharmaceutical products in the United States. App. 66a.

A manufacturer seeking to market a new drug must file with the FDA a New Drug Application ("NDA") demonstrating the safety and efficacy of the product. *Id.* (citing 21 U.S.C. § 355(b)). Such new drugs may be covered by a patent. The NDA filer must identify any patent that claims the drug for which FDA approval is being sought, or that claims a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. App. 66a-67a.

The FDA maintains a list of approved "Reference Listed Drugs" in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." App. 67a. Once the FDA approves an NDA, the drug may be listed in the Orange Book, along with any patent that: (1) claims the approved

drug; and (2) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engages in the manufacture, use, or sale of the drug. *Id.* (citing 21 U.S.C. § 355(j)(7)(A)(iii)).

II. Generic Drugs

The Hatch-Waxman Act was passed in 1984 to speed the entry of less expensive generic drugs to the market. App. 69a. *See also In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Generic drugs are virtually identical to their brand-name counterparts, but are typically much less expensive. App. 68a-69a.

Hatch-Waxman permits a drug company to file an "Abbreviated New Drug Application" ("ANDA") that may rely on safety and efficacy data previously submitted by the NDA filer regarding a particular drug. App. 69a.

However, brand drug companies have exploited certain features of Hatch-Waxman to wrongfully block and delay generic competition and thereby inflict massive overcharges on purchasers. If a patent is listed in the Orange Book for a particular drug, an ANDA filer, seeking to market a generic version before the patent has expired, must certify that each listed patent is either invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification"). App. 70a-71a (citing 21 U.S.C. § 355(j)(2)(A)(vii)). A Paragraph IV certification allows the patent holder,

by filing a patent infringement suit within 45 days, to delay FDA approval of the ANDA automatically for up to 30 months. App. 71a. The patent holder can obtain this delay without any showing that its patent is valid or infringed by the proposed generic. App. 72a. Because generic drugs are significantly cheaper than brand drugs, and typically are substituted rapidly for the brand, brand name drug companies have very strong financial incentives to delay generic competition by any means, including by filing patent infringement suits regardless of their merits. App. 72a-73a.

In addition, branded drug companies can abuse the citizen petition process before the FDA by asking the agency to investigate the safety and efficacy of a proposed generic drug. 21 C.F.R. § 10.30. Merely filing a petition can cause a time-consuming and often unnecessary review, substantially delaying approval of a generic's ANDA. App. 92a. Branded drug companies thus have an incentive to lodge such petitions regardless of their merit. The FDA's chief counsel has noted repeated abuses of the citizen petition process to delay generic competition. App. 92a-93a.

III. Defendants' Scheme to Monopolize

DDAVP is the brand name of the prescription drug desmopressin acetate, an anti-diuretic used to manage diabetes insipidus, excessive urination and thirst, and bed wetting. App. 59a. In 1969-70, Ferring obtained two patents related to this drug:

patent no. 3,454,549 ("the '549 Patent") and patent no. 3,497,491 ("the '491 patent"). App. 75a.

Respondents sold tens of millions of dollars of desmopressin products during the 1980s. However, Defendants foresaw that, once the '549 and '491 patents expired, that cash stream would dry up as less expensive generics captured the market. App. 76a. Defendants undertook a multifarious scheme to block generic competition and preserve and extend their monopoly on desmopressin products. *Id.*

A. Fraud on the PTO

On December 17, 1985, Ferring applied for a patent claiming a tablet form of desmopressin acetate, absorbed through the stomach and intestines (the "'398 Application"). App. 78a.

The PTO was reluctant to issue the patent, however, and the application was rebuffed multiple times. The PTO examiner assigned to the '398 Application was concerned that the '491 patent's disclosure of "peroral" application suggested oral administration for absorption via the stomach, since "peroral" means "through the mouth." App. 79a. The examiner knew that Ferring had an economic incentive to seek further patent protection and accordingly, specifically requested evidence from a "non-inventor" to support the claim that the '398 was not obvious in light of prior art. App. 79a-80a. In addition, the PTO's Manual of Patent Examining Procedure also stated that a declarant's interest

warranted close scrutiny. App. 84a. Thus, from the very outset, Ferring was on notice of the PTO's concern about declarants' bias.

Nevertheless, over the course of the next four years while the '398 patent application was prosecuted before the PTO, Ferring submitted a series of declarations to convince the PTO to issue a patent, while repeatedly concealing that the declarants had financial and other ties to Ferring. App. 80a-84a.

On November 21, 1990, Ferring submitted a final set of declarations to the PTO, with each declarant opining why, in his professional opinion, the '398 Application was not obvious in light of the prior art. App. 82a. These same declarations, however, were riddled with fraudulent omissions. They failed to disclose that four of the declarants were former Ferring employees or had received research funds from the company; that two of the declarations supposedly being submitted by alleged "non-inventors" were drafted with the inventor's aid; and that one declarant had *no* expertise in DDAVP tablets and could not recall having done any research on drug delivery systems or on absorption of peptides in the gastrointestinal tract – two issues central to evaluating whether the '398 Application was obvious in light of prior art. App. 82a-83a.

The patent examiners were not, and could not have been, aware of the declarants' multiple, undisclosed ties to Ferring. App. 82a.

On April 8, 1991, the PTO – after repeatedly rejecting the '398 Application and only after receiving the final set of fraudulent declarations – reversed course and allowed the '398 patent to issue. App. 84a.

B. The Sham Orange Book Listing

Although the '398 patent had been obtained by fraud, Defendants amended the listing for DDAVP in the Orange Book to include the patent. App. 84a-86a. Defendants knew that by listing the patent, they could block any potential generic competitor filing a Paragraph IV certification for 30 months merely by filing suit. App. 70a-73a, 85a-87a.

After receiving FDA approval, DDAVP tablets were introduced to the market. Sales for DDAVP tablets grew from $78 million in 2000, to $125 million in 2002, to $180 million in 2004. App. 86a.

C. The Sham Litigation

Two potential competitors – Barr Laboratories, Inc. ("Barr") and Teva Pharmaceuticals USA, Inc. ("Teva") – sought to market generic versions of DDAVP. Each filed an ANDA and a Paragraph IV certification certifying that the '398 patent was either invalid or would not be infringed by its respective generic formulations. App. 87a, 91a.

Despite Barr's certification, and despite the fact that the '398 patent had been obtained by fraud,

Ferring and Aventis sued Barr and alleged infringement of the '398 patent. App. 88a-89a. Ferring also sued Teva. App. 91a. These suits triggered the 30-month stay provisions of Hatch-Waxman. App. 71a-73a, 88a, 91a.

In April 2004, Barr moved for summary judgment on the issue of inequitable conduct. The district court held on Feb. 7, 2005, that the '398 patent was unenforceable due to "***clear and convincing evidence***" of "***deceit... practiced over a long period of time by more than one person***" which "***appears to have been outcome determinative.***" App. 88a-89a (emphases added) (*quoting Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 WL 437981, *10 (S.D.N.Y. Feb. 7, 2005) ("*Ferring I*")). The court found that, "the PTO ***must have relied substantially*** on these declarations, as there ***is no alternative explanation*** offered for the Board's final allowance of the claims after several prior rejections by the PTO." App. 89a (emphases added).[9]

The Court of Appeals for the Federal Circuit affirmed on February 15, 2006. App. 89a. In a strongly-worded opinion, the Federal Circuit found that: (a) the failure to disclose the past relationships between the declarants and Ferring was "*highly material* as a matter of law" because the PTO was specifically concerned about bias and the objectivity

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[9] *See also Ferring I*, 2005 WL 437981, at *9-10.

of those trying to distinguish prior art, and therefore had specifically requested "non-inventor" affidavits;[10] (b) the omissions were made with an intent to deceive;[11] and (c) the repeated omissions over a prolonged period of time "support[] a conclusion that the past relationships ***were deliberately concealed.***"[12]

> The Federal Circuit further found that:
>
> [T]he second set of declarations... plagued with even more undisclosed affiliations than the first set, *was absolutely critical in overcoming the Board's obviousness rejection.*
>
> * * *
>
> *Not only were these declarations pivotal, they were essentially opinions that were supported largely by the declarants' own scientific expertise and little else.*

Id. at 1189 (emphases added).

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[10] *Ferring II*, 437 F.3d at 1190 (emphasis added).

[11] *Id.* at 1190-93.

[12] *Id.* at 1193 (emphasis added).

D. The Sham Citizen Petition

As part of Defendants' over-arching scheme, on February 2, 2004, Ferring filed a sham citizen petition with the FDA pursuant to 21 C.F.R. § 10.30, asking the agency to require Barr to submit additional tests before its generic product could be approved. App. 93a-94a. Although Ferring certified that it had included "all information... known to the petitioner [] unfavorable to the petition," App. 95a, it failed to disclose a study sponsored by Aventis (the "Aventis Study") that directly undermined the petition. App. 96a.

Ferring knew or should have known of the Aventis Study, but did not disclose it; and Aventis knew or should have known that the petition had omitted the Aventis Study, but did nothing to correct it. App. 96a.

Ferring I was issued on February 7, 2005. The Court stated that the citizen petition – then still pending – had been "motivated by a desire to keep out competition for as long as possible." 2005 WL 437981, at *17. Despite the Court's conclusions concerning the "fraudulent omissions" and other blatant misconduct used to obtain the '398 patent, Aventis and Ferring allowed the sham petition to remain on file. The '398 patent had been held unenforceable, but the sham petition blocked Barr's generic product. App. 97a-100a.

On July 1, 2005, the FDA rejected the citizen petition as lacking "***any basis***" and explicitly relied on the Aventis Study. The same day, Barr received final FDA approval, and launched its cheaper generic DDAVP tablets. App. 100a. After the expiration of Barr's 180-day exclusivity period, Teva and another generic competitor, Apotex Corp., also came to market. *Id.*

IV. Procedural History

Plaintiffs brought suit as direct purchasers of DDAVP tablets. They filed their amended complaint on March 31, 2006, asserting a single claim for monopolization in violation of 15 U.S.C. § 2. App. 104a-107a.

Plaintiffs requested relief in the form of overcharges pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15. App. 108a. Plaintiffs alleged that but for Defendants' conduct, generic competition would have occurred earlier than it did. App. 102a-103a. However, due to Defendants' conduct, generic competition did not begin until July 1, 2005 – the date the citizen petition was denied and Barr received final FDA approval.[13]

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[13] Defendants and Amici make it sound as though the bulk of the alleged injuries occurred before the patent was ruled unenforceable (or the citizen petition filed). *E.g.*, Petition at 16. However, Plaintiffs only allege that generic entry would have occurred earlier than it did. App. 102a. This allegation is

Defendants moved to dismiss, arguing that Plaintiffs, despite their undisputed status as direct purchasers, lacked standing to bring this antitrust case. Defendants argued that no purchasers, direct or otherwise, should have standing to bring a federal antitrust action for overcharges resulting from fraud on the PTO. Instead, argued Defendants, only alleged injured competitors – who would have separate and different claims for lost sales and profits – should have such antitrust standing. Aventis separately argued that it was not sufficiently implicated in any wrongdoing, even though it had, for example, participated in planning the citizen petition. The district court dismissed, also deciding (without affording Plaintiffs any notice or opportunity to be heard) that Plaintiffs had failed to state a claim. App. 35a-55a.

Plaintiffs appealed to the Court of Appeals for the Second Circuit. Defendants moved to transfer the appeal to the Federal Circuit.

The Court of Appeals for the Second Circuit denied the motion to transfer, and vacated and remanded, finding that Plaintiffs had satisfied the standards for antitrust standing. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 688-92 (2d Cir. 2009), *reprinted in* App. 1a-34a. The court emphasized that a *Walker Process* theory sounds in antitrust. App. 22a-23a. Further, the

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sufficient to allege antitrust injury.

court observed that "*Walker Process* does not necessarily suggest [] a limit" on standing, but rather calls for the patentee to "answer" for its wrongdoing "to *those injured by any monopolistic action*[.]" App. 23a. (emphasis in original) (quoting *Walker Process*, 382 U.S. at 176).

The Second Circuit also found that it, rather than the Federal Circuit, had jurisdiction. App. 8a-16a. The court applied the *Christianson* test, observing that if "there are reasons completely unrelated to the provisions and purposes of federal patent law why [Plaintiffs] may or may not be entitled to the relief they seek under their monopolization claim," then "the claim does not arise under federal patent law" and the Federal Circuit lacks jurisdiction. App. 9a (citing *Christianson*, 486 U.S. at 812).

The court also found that Plaintiffs' fourth theory of liability – the sham citizen petition filed with the FDA – "does not turn on a substantial question of patent law." App. 11a. Plaintiffs could sustain their prima facie case for monopolization by demonstrating that Defendants' sham citizen petition was not entitled to *Noerr*[14] immunity because it was objectively baseless. App. 11a-13a. Further, Plaintiffs were injured by the citizen petition because it delayed the availability of generic

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[14] *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) ("*Noerr*").

DDAVP. Indeed, for a substantial period of time, the patent had already been ruled unenforceable, removing any potential patent-related defense. 14a-16a.

The court then sustained each of Plaintiffs' theories under Rule 12, upheld Plaintiffs' allegations against Aventis, and therefore did not reach Plaintiffs' due process argument. App. 25a-34a.

Defendants have now petitioned for certiorari, seeking review only of whether the appeal should have been transferred to the Federal Circuit.

ARGUMENT

I. The Second Circuit Faithfully Followed The Standard Announced In *Christianson*

A. *Christianson* Forecloses Federal Circuit Jurisdiction For Well-Pleaded Complaints Which Do Not Depend On Patent Law

1. The Court of Appeals faithfully followed this Court's decision in *Christianson*. Plaintiffs' sole claim for monopolization was supportable without necessarily depending on patent law because Plaintiffs would be entitled to relief by virtue of their citizen petition theory alone. If the Complaint were limited to the sham citizen petition theory, Plaintiffs could still prove Defendants' liability under the Sherman Act and obtain damages under the

Clayton Act, all without having to resolve any issue of patent law. In essence, Defendants argue that this Court should abandon the well-pleaded complaint rule long used as the benchmark for Federal Circuit jurisdiction.

As a general matter, the Second Circuit has jurisdiction over final decisions from district courts within its aegis. *See* 28 U.S.C. §§ 1291, 1294.

In contrast, the Federal Circuit's jurisdiction is strictly limited, extending to cases where district court jurisdiction is based on 28 U.S.C. § 1338. 28 U.S.C. §1295(a)(1). Section 1338, in turn, grants jurisdiction for cases "arising under any Act of Congress relating to patents[.]" 28 U.S.C. § 1338(a).[15] The "arising under" language of § 1338 is construed akin to the "arising under" language which forms the basis for federal question jurisdiction, 28 U.S.C. § 1331. Thus, jurisdiction under § 1338 extends:

> only to those cases in which a well-pleaded complaint establishes either that [1] federal patent law creates the cause of action or [2] that the plaintiff's

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[15] The Federal Circuit has observed that Congress intended it to apply the long-standing "canon of construction" to "strictly construe [its] jurisdiction." *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1556 (Fed. Cir. 1987) (quoting S. Rep. No. 275, 18-19, *reprinted in* 1982 U.S.C.C.A.N. 11, 28-29), *vacated on other grounds*, 486 U.S. 800 (1988).

> right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.

Christianson, 486 U.S. at 809. However, "[n]ot all cases involving a patent-law claim fall within the Federal Circuit's jurisdiction." *Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 834 (2002). It is not enough that a complaint may reference theories which incorporate patent law:

> If on the face of a well pleaded complaint there are reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff may or may not be entitled to the relief it seeks, then the claim does not "arise under" those laws.

Christianson, 486 U.S. at 810 (internal quotes and original alternations omitted). "Thus, a claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories." *Id.*

2. The decision *sub judice* fully comports with *Christianson.* The Second Circuit found, and Defendants agree (Petition for a Writ of Certiorari ("Petition") at 11), that "because the plaintiffs have

filed an antitrust suit, patent law does not create the cause of action." App. 9a.

Thus, to meet their burden of establishing Federal Circuit jurisdiction, Defendants had to meet the second test under *Christianson* – that "[P]laintiff[s'] right to relief necessarily depends on resolution of a substantial question of federal patent law." 486 U.S. at 809.

Here, Plaintiffs' right to relief depends on showing a violation of Section 2 of the Sherman Act, *viz.*, (1) the possession of monopoly power; and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident, *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966), and antitrust injury. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 & n.9 (1969).

The Court of Appeals found that Plaintiffs' sham citizen petition theory did not depend on patent law. App. 11a-13a. Although petitioning a government agency may ordinarily be protected, if such acts are "a... sham to cover what is... nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified." App. 12a (alterations in original) (quoting *Noerr*, 365 U.S. at 144). Because the sham citizen petition theory supports a claim under Section 2 without

necessitating patent law, Federal Circuit jurisdiction is unavailable.

Although Plaintiffs may have had *additional* theories which involve patent law, the existence of one theory that is independent of patent law meant that the Second Circuit correctly retained jurisdiction, and correctly denied Defendants' motion to transfer.

B. Defendants' Proposed New Rules Contradict *Christianson*

1. Defendants mistakenly believe the Second Circuit erred because, in their view, the "'core' of [P]laintiffs' claim" is Defendants' fraudulent procurement and enforcement of their patent. Petition at 13. Defendants seek to supplant the *Christianson* test by allowing defendants to pick which parts of the complaint they view as more "important" and site jurisdiction accordingly.

It is not for Defendants to decide which of Plaintiffs' theories are more important. Plaintiffs are "the master[s] of the complaint"[16] and Defendants cannot recast Plaintiffs' allegations for them.[17]

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[16] *Holmes*, 535 U.S. at 831.

[17] *Tennessee v. Union & Planters' Bank*, 152 U.S. 454, 464 (1894) ("a suggestion of one party, that the other will or may set up a claim under the Constitution or laws of the United States, does not make the suit one arising under that Constitution or

In focusing on the allegations of fraudulent patent procurement, Defendants mistake them for a separate claim. These allegations describe merely one of several means – one theory among several – by which Defendants obtained and maintained monopoly power. While some of Defendants' misdeeds involved abuses of patent rights, others, like the citizen petition, did not. This case thus stands in stark contrast to the cases Defendants cite (Petition at 13 n.4), which involved claims necessarily dependent on patent law,[18] or sought relief available only under patent law.[19]

Amici also suggest using Rule 12 to distinguish between claims and theories (Brief of Intellectual Property Owners Association as *Amicus Curiae* in Support of Petitioners at 12-13), but Defendants could not win dismissal of Plaintiffs' monopolization claim even if Plaintiffs' patent-related allegations were found wanting. Indeed,

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those laws."). Nor can Defendants recharacterize the Complaint by picking out language from the Court of Appeals' decision. Cf. Petition at 17 n.5.

[18] *E.g., Hunter-Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1329 (Fed. Cir. 1998) (claim arose under patent law because "a required element ... necessarily depends on a question of federal patent law"), *overruled on other grounds, Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

[19] *E.g., Jacobsen v. Katzer*, 535 F.3d 1373, 1377 (Fed. Cir. 2008) (complaint contained claims for declaratory judgment that patent was not infringed or was invalid).

Defendants' original joint motion to dismiss challenged only Plaintiffs' standing to assert *Walker Process* fraud. Had Defendants prevailed (and had the District Court not improperly exceeded that motion and dismissed the whole case), Plaintiffs' claim for relief would have survived.

Indeed, in belittling the citizen petition, Defendants minimize the public harm wreaked by the use of such petitions to delay the entry of cost-saving generics. The concern was serious, as attested to by both the Federal Trade Commission and the FDA itself. App. 92a-93a. Such petitions exemplify Judge Bork's concern that "[t]he modern profusion of... governmental authorities offers almost limitless possibilities for abuse[.]" Robert H. Bork, THE ANTITRUST PARADOX 347 (1993).

Moreover, the relief Plaintiffs seek – a declaration that "Defendants' actions... to be a violation of Section 2 of the Sherman Act" and overcharge damages (App. 107a-108a) – can be granted whether the monopolistic conduct is the sham citizen petition alone or Defendants' fraud on the PTO.[20] The Second Circuit thus kept the focus on

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[20] Defendants excerpt Plaintiffs' Complaint out of context (Petition at 15-16) to give the appearance of a patent claim. In addition to alleging four theories of monopolization, Plaintiffs also alleged an "overarching scheme" by Defendants. App. 74a. As with most schemes, Defendants' means overlapped to a common end: "to protect their monopoly." App. 59a. This is akin to *Christianson*'s complained-of "course of conduct to

"claims, not theories," and just because some particular theory "might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." App. 15a (quoting *Christianson*, 486 U.S. at 811 (internal citations omitted)).

The Second Circuit's analysis thus accords with *Christianson*. There, the plaintiff alleged that various actions were in violation of the antitrust and other laws. *Id.* at 805-06. The defendant had appealed to the Federal Circuit, claiming jurisdiction by focusing on one theory outlined in the complaint said to depend on patent law. *See id.* at 806, 811. The Supreme Court, however, noted that the theory the defendant emphasized was "only one of several", and that plaintiffs could also prevail under other theories. *Id.* at 811. Like here, the presence in the complaint of an "alternative, non-patent theory

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illegally extend its monopoly", which was also supported by separate theories and various separate and interlocking actions, some of which raised patent questions while others did not. *Christianson*, 486 U.S. at 810. Defendants also misleadingly suggest that Plaintiffs seek a judgment "declaring *all* of defendants' alleged actions ... to be unlawful." (Petition at 15-16) (emphasis in original). To prevail, Plaintiffs only need *some* of Defendants' "actions" to be declared unlawful. The citizen petition itself involved many such "actions," including, *inter alia*, planning and submitting the petition, the continued concealment of Defendants' own study that undermined their petition, and its continued prosecution. App. 93a-96a.

compels the conclusion that the [antitrust] claim does not 'arise under' patent law[.]" *Id.* at 813.

2. Defendants also claim the Second Circuit erred because, in their view, damages predating the loss of their patent case depend on patent law. The Second Circuit correctly observed that "this fact lacks jurisdictional significance." App. 15a. Plaintiffs seek a declaration that Defendants violated 15 U.S.C. § 2, and Plaintiffs' suffered overcharges. A claim under Section 2 is stated simply by proving a violation and the fact of injury. Defendants' point merely goes to the quantum of damages. So long as Plaintiffs make out a case for some damages, they have stated a claim for relief.[21]

Defendants thus seek to create a new rule requiring every penny of alleged damages to be independent of patent law, or else the case must be transferred to the Federal Circuit. *Christianson* nowhere imposes such a requirement. Indeed, *Christianson* does not discuss damages at all, simply the gravamen of liability. *See, e.g., Christianson*, 486 U.S. at 811 (identifying elements for liability under Sherman Act § 2). Defendants cherry-pick two words in *Christianson*: "overall success,"[22] and take them to mean "all" relief. But the full quote

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[21] To state a claim under the Sherman Act, Plaintiffs need only show *some* antitrust injury, the exact quantity is a question of damages. *See Zenith Radio*, 395 U.S. at 114 & n.9.

[22] *Christianson*, 486 U.S. at 810.

undermines Defendants' gloss: "The patent-law issue, while arguably necessary to at least one theory under each claim, is not necessary to the overall success of either claim."[23] In other words, patent law was not necessary to the success of either claim "viewed as a whole."[24]

Such a rule fully comports with the basis for the narrow jurisdiction of the Federal Circuit, which was empowered to hear only cases which present substantial questions of patent law. Expanding that jurisdiction, as Defendants would have it, would destroy the careful balance struck by Congress. *See* S. Rep. No. 97-275, at 4 (1982), *reprinted in* 1982 U.S.C.C.A.N. 11, 14 ("it is not the committee's judgment that broader subject matter jurisdiction is intended for this court").

That danger is evident here, where Plaintiffs' injury can be attributed to the citizen petition alone without relying on any patent law, because the citizen petition was a material cause of Plaintiffs' injury.[25] That is, for the period following the ruling of the unenforceability of the '398 patent, *no patent*

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[23] *Id.*

[24] MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 883 (11th ed. 2003) ("overall").

[25] *Zenith Radio*, 395 U.S. at 114 n.9 ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury").

issues existed.[26] Even beforehand, the sham citizen petition was a material cause of Plaintiffs' injuries.[27]

II. There Is No Circuit Split

Defendants next claim that the decision below conflicts with decisions of the Federal Circuit and the Seventh Circuit. That is incorrect. These courts are all in accord. Indeed, all courts, including the Federal Circuit, recognize that a claim supported by

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[26] Defendants also claimed below that to prove an "intent to monopolize" via the citizen petition, Plaintiffs must show Defendants believed that the patent was likely to be ruled unenforceable, which they claim involves patent law. The Second Circuit correctly noted that Defendants left the sham petition on file after losing the patent case, exposing their intentions. App. 14a. Moreover, there is no requirement to prove an intent to monopolize in the sense Defendants suggest, for "no monopolist monopolizes unconscious of what he is doing." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 n.28 (1985). In any event, proof that Defendants subjectively doubted that their patent alone would stop generic competition would not necessarily implicate substantive patent law, merely Defendants' state of mind, which could be proven circumstantially, including through their very act of filing the sham citizen petition.

[27] Defendants point to the definition of the proposed class which includes purchasers to the beginning of the statutory period in 2001 (Petition at 16), but this merely recites those who may be members of the class. The class is defined as all direct purchasers who were injured by a delay in generic entry – precisely what the citizen petition accomplished.

even a single non-patent theory does not arise under patent law.[28]

1. First, Defendants cite to *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008). There, the Second Circuit had transferred a case brought by indirect purchasers to the Federal Circuit. In doing so, however, the Second Circuit distinguished between the direct purchasers (who had raised a single claim based on multiple theories and therefore were not transferred), and the indirect purchasers, who had amended their complaint to add an additional state law claim of monopolization, supported solely through allegations of *Walker Process* fraud. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir. Nov. 7, 2007) (Respondents' Appendix 2a); *see also Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 05-2851-CV(L), 05-2852-CV(CON)), __ F.3d __, 2010 WL 1710683, *3 n.10 (2d Cir. Apr. 29, 2010).

After receiving the indirects' appeal, the Federal Circuit in *Ciprofloxacin* agreed that the indirects' state-law claim for monopolization, based on *Walker Process* (and nothing else), gave it jurisdiction. 544 F.3d at 1330 n.8. It did not hold, as Defendants suggest, that the mere presence of

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[28] *See, e.g., Clearplay, Inc. v. Abecassis*, 602 F.3d 1364, 1367-68 (Fed. Cir. 2010); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 200 (2d Cir. 2006).

Walker Process allegations creates jurisdiction. Two circuits at opposite ends of the same transfer can hardly be said to be in conflict.

2. Defendants next cite the decisions in *U.S. Valves, Inc. v. Dray*, 190 F.3d 811 (7th Cir. 1999), *upon transfer*, 212 F.3d 1368 (Fed. Cir. 2000), but have the teachings of those cases backward. There, the plaintiff could establish the defendant's breach of contract only by proving patent infringement. The issue of infringement was inextricably tied to plaintiff's ability to prove liability and *all* of the relief it sought. That is not the case here at all.

U.S. Valves and Dray contested payments due under a patent license agreement between them. Dray had patented an "internal piston valve" and had granted an exclusive license to U.S. Valves. 190 F.3d at 812. However, Dray then began selling valves on his own, both the internal piston valves and another type, sliding ring valves. *Id.* U.S. Valves sued for breach of the patent license, claiming that *both types of valves* which Dray sold had infringed the licensed patents. *Id.* Dray conceded that he had sold some internal piston rings covered by the patents, and the trial court awarded damages accordingly. *Id.*

U.S. Valves appealed to the Seventh Circuit, and Dray moved for transfer. The Seventh Circuit held that U.S. Valves' claim required "examin[ing] the patent and determin[ing] which valves are

covered and whether the patent was infringed." *Id.* at 814. The only way to determine whether there was a breach of contract *at all* vis-à-vis the sliding ring valves was relying on patent law. For the other type of valves, infringement was conceded (and if it had not been, patent law would have been a necessarily component there as well). Thus, the appeal was transferred to the Federal Circuit.

Upon transfer, the Federal Circuit reached the same conclusion. 212 F.3d at 1372.

Defendants portray these companion cases as if the jurisdictional decision rested on the determination that a "*portion* of U.S. Valves' infringement claim deal[t] with Dray's sale of sliding ring valves[.]" Petition at 23 (emphasis in original).

Not so. *No* damages were available to U.S. Valves without invoking patent law. The allegations of breach in U.S. Valves' complaint – with respect to *both* types of valves – required patent law because one needed to determine if any valves sold had infringed. The court focused on the sliding ring valves because they were the only products whose infringement remained in question. Dray had conceded infringement for the other valves, which was the basis for the district court's decision. But that concession was of no jurisdictional significance. A well-pleaded complaint seeking damages for the infringing internal piston valves would also rely on patent law. In other words, getting damages for both valves depended on patent law.

Dray is not in conflict with the Second Circuit, but in accord.

3. Finally, Defendants attempt to find a circuit split based on the Federal Circuit's decision in *Davis v. Brouse McDowell, L.P.A.*, 596 F.3d 1355 (Fed. Cir. 2010), but that decision merely applies *Christianson*. *See Davis*, 596 F.3d at 1359 (citing *Christianson*, 486 U.S. at 808-09). The court also found that a claim is an "aggregate of operative facts *giving rise to a right enforceable by a court*." *Davis*, 596 F.3d at 1360 (emphasis added). The court held the plaintiff there sought to lay claim to two different types of rights – each of which entailed distinct forms of injury.

In *Davis*, the plaintiff brought a malpractice suit against the defendant law firm, alleging what the Federal Circuit viewed as two distinct types of legal malpractice: (1) alleged missteps relating to her application for a U.S. patent and (2) failure to timely file a foreign patent application. *Id.* at 1360. The plaintiff was thus complaining of the loss of rights of two different characters: U.S. patent rights and foreign patent rights, and accordingly was seeking two types of relief: (1) lost in-U.S. patent royalties and (2) lost ex-U.S. patent royalties.[29] Establishing

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[29] Rights under foreign patents do not arise under U.S. patent law. Cf. *Voda v. Cordis Corp.*, 476 F.3d 887, 894 (Fed. Cir. 2007) (distinguishing jurisdictional basis for U.S. and foreign patent claims).

wrongful deprivation of a U.S. patent and its attendant royalties required proving "[t]he patentability of [plaintiff's] inventions" which was "controlled by U.S. patent law," *Davis*, 596 F.3d at 1362, and the Federal Circuit had jurisdiction.

In this light, *Davis* accords with the Second Circuit, which also examines the various *types* of rights and relief which the well-pleaded complaint seeks. Cf. *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194-95 (2d Cir. 2005) (finding plaintiff who sought relief, federal in character and which existed only under federal law, had stated a claim arising under federal law).

Unlike Davis, who sought to establish multiple rights in her complaint, Plaintiffs here seek relief of one character – a finding that Section 2 of the Sherman Act was violated and that Plaintiffs are entitled to antitrust damages. That an additional quantum of damages of the same character might be available by referencing patent law does not change that jurisdictional analysis. Nothing in *Davis* is to the contrary.

The more recent decision in *Clearplay, Inc. v. Abecassis*, dispels any doubt that the Federal Circuit, like the Second Circuit, recognizes the distinction between claims and theories, and that it lacks jurisdiction when the claims in the complaint can be supported by non-patent theories. 602 F.3d at 1368-69. Although there it was "*possible* that patent law issues could arise in the course of litigating any

one of [plaintiff's] claims, it is equally clear that none of those claims *necessarily* turns on an issue of patent law." *Id.* at 1368 (emphases added). It therefore lacked jurisdiction.

The court also rejected a contention, like that made by Defendants here, that the alleged centrality of patent issues warranted jurisdiction:

> While it may be true, in a holistic sense, that the dispute between these parties is patent-based, *the Supreme Court's decision in Christianson embraces a distinctly non-holistic approach to "arising under" jurisdiction.* It is not enough that patent law issues are in the air. Instead, *resolution of a patent law issue must be necessary to every theory of relief under at least one claim in the plaintiff's complaint. And that is not so in this case.*

Id. at 1369 (emphases added).

The Second Circuit and the Federal Circuit therefore agree: if patent law is not essential to any claim, the Federal Circuit has no jurisdiction, even if patent issues are prominent in the complaint. Thus, Defendants' effort to manufacture a circuit split is unavailing.[30]

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[30] The unanimity of recent appellate decisions on point belies

III. Concerns About Forum Shopping And The Uniformity Of Patent Law Do Not Justify Deviating From The Well-Pleaded Complaint Rule

A. The *Christianson* Rule Defines Federal Jurisdiction and Prevents Forum Shopping

Defendants next argue that *Christianson* should be disregarded on policy grounds because it makes it too difficult to haul plaintiffs to the Federal Circuit. (Petition at 17-19). They also argue that Congressional intent for uniformity in patent law will somehow be frustrated if all antitrust cases with patent elements are not sent to that court. (Petition at 27-29). However, Congress intended to grant the Federal Circuit only *limited* jurisdiction to aid nationwide uniformity in *patent* law. *See* S. Rep. No. 97-275 at 4, *reprinted in* 1982 U.S.C.C.A.N. at 14. Congress was particularly mindful of criticism that the Federal Circuit might inappropriately assert jurisdiction over cases under the antitrust laws. *See* Ronald S. Katz & Adam J. Safer, *Should One Patent*

Amicis' claim of doctrinal uncertainty. (Brief of the Biotechnology Industry Organization, et al. as *Amici Curiae* in Support of Petitioners, 12-13) ("BIO Brief"). Although they cite some old statements expressing such concern (including some pre-dating Congress's creation of the Federal Circuit), they cite no *recent* source claiming that courts or practitioners are befuddled.

Court Be Making Antitrust Laws for the Whole Country?, 69 ANTITRUST L.J. 687, 689-90 (2002).

The Supreme Court has heard and rejected Defendants' "uniformity of patent law" argument twice before. The defendants in *Christianson*, like Defendants here, contended that such concerns counseled sending that case to the Federal Circuit, despite the presence of a non-patent theory which sustained the complaint. This Court concluded, however, that Congress had determined the relevant focus for granting jurisdiction to the Federal Circuit was "by reference to the well-pleaded complaint, not the well-tried case." 486 U.S. at 813-14. The legislative history confirmed such a result. *Id.* (citing H.R. Rep. No. 97-312 at 41 (1981)). Thus, the jurisdictional mandates of § 1295(a)(1) and § 1338, and not Defendants' policy preferences, establish the means to ensure uniformity of patent law. *Id.*

Similarly, in *Holmes Group*, the Supreme Court rejected an attempt to expand Federal Circuit jurisdiction out of solicitude for uniformity of patent law. "Our task here is not to determine what would further Congress's goal of ensuring patent-law uniformity, but to determine what the words of the statute [§ 1295(a)(1)] must fairly be understood to mean." 535 U.S. at 833.

Likewise, the Federal Circuit has observed that the goal of "uniformity in the patent laws" is not hindered where "statutory limitations on the jurisdiction of this court and the federal district

courts, in conjunction with the well-pleaded complaint rule" mean that a case does not "arise under" patent law. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 599 F.3d 1277, 1285 (Fed. Cir. 2010). That may mean some patent questions will be addressed by regional circuits, but those courts are "perfectly competent... to determine patent 'questions' or 'issues' that may occasionally arise in cases within their jurisdiction." *Christianson*, 822 F.2d at 1552 n.10 (citations omitted).

Moreover, Federal Circuit guidance is unnecessary here. Defendants here have already obtained a ruling from the Federal Circuit that the '398 patent was unenforceable, finding evidence that Defendants "*deliberately concealed*" information which was "*pivotal*" and "*highly material as a matter of law*[.]" *Ferring II*, 437 F.3d at 1189, 1190, 1193 (emphases added).[31]

In addition, the Federal Circuit has held that a plaintiff may assert an antitrust claim invoking *Walker Process* even if it was not directly the subject of a patent enforcement action (and hence lacked

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[31] Thus, the extended discussion by Amici concerning regional circuit law on inequitable conduct is beside the point. BIO Brief at 16-21. Although Amici bemoan that regional circuits' patent law has been "frozen" since the 1980s (*Id.* at 19), regional circuits confronting patent issues can do precisely what the Second Circuit did here – look to Federal Circuit precedent. *See* App. 26a-30a (citing Federal Circuit precedent seven times).

standing for a patent claim). *Hydril Company LP v. Grant Prideco LP,* 474 F.3d 1344 (Fed. Cir. 2007).

Defendants raise the specter of artful pleading, but a plaintiff is not going to be able to circumvent Federal Circuit jurisdiction where such jurisdiction is mandated. Should a plaintiff bring a true patent-based claim (*e.g.*, seeking infringement damages or a declaration of inventorship), it cannot defeat jurisdiction by omitting an essential question of patent law. *Christianson*, at 809 n.3 (citation omitted). Thus, if some future plaintiff should engage in artful pleading, a court will simply read the necessary patent law question into the complaint.

By the same token, a plaintiff who has no good faith, non-patent related basis to allege monopolization cannot simply make something up.

Defendants here, however, did file the citizen petition. They may dispute it was a sham, but they cannot dispute they filed it, and that it was rejected as lacking any basis. Plaintiffs' claim for monopolization does not need patent law to survive. There is simply no reference to patent law which Plaintiffs were required to plead but omitted. Furthermore, Plaintiffs, "master[s] of [their] complaint[,]" are not required to bring patent claims, and "by eschewing claims based on [patent] law," are

entitled to have the cause heard outside the Federal Circuit. *Holmes Group*, 535 U.S. at 831.[32]

Plaintiffs can thus hardly be accused of forum shopping. Rather, they appealed their antitrust case to the regional court of general jurisdiction. That is what Congress intended them to do. Congress was in fact concerned that a plaintiff may do the reverse: joining a patent claim to "avail [itself] of the jurisdiction of the Federal Circuit in avoidance of the traditional jurisdiction and governing legal interpretations of a regional court of appeals." S. Rep. 97-275, at 20, *reprinted in* 1982 U.S.C.C.A.N. at 30.

B. Deciding Whether Plaintiffs Have Antitrust Standing Does Not Call for Guidance from the Federal Circuit

Though Defendants do not seek certiorari on the question, they claim that the issue of whether Plaintiffs have antitrust standing should have been decided in the first instance by the Federal Circuit (Petition at 19-21).

First, the nature of the question on appeal is irrelevant. Jurisdiction does not "rest on the subject

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[32] Amici cite to *City of Chicago v. International College of Surgeons*, but the plaintiff there unquestionably pled "a number of federal constitutional claims" arising under federal law. 522 U.S. 156, 160 (1997). That these were federal claims, not theories, was not even discussed.

matter of the judge's decision, but rather the well-pleaded complaint." *U.S. Valves*, 190 F.3d at 813; *see also Scherbatskoy v. Halliburton, Co.*, 125 F.3d 288, 291 (5th Cir. 1997).

Second, the question of whether Plaintiffs – direct purchasers who allege they have been overcharged – have antitrust standing to bring an antitrust claim, is a question of antitrust law, not patent law. The Federal Circuit itself has declared itself bound to follow the law of the regional circuit on whether a plaintiff has antitrust standing. *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1362 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). Thus, purported concerns of uniformity of patent law are not even implicated. Here, the Second Circuit applied conventional antitrust standing analysis, and found that Plaintiffs had standing. App. 16a-25a.

The decision in *DDAVP* comports with basic antitrust principles. The direct purchasers seek to recover overcharges arising from Defendants' monopolistic conduct and pricing, and are thus efficient enforcers of the antitrust laws. App. 16a-20a. *See also Illinois Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977) (observing that to promote efficiency, deterrence, and antitrust enforcement, direct purchasers were "elevat[ed]... to a preferred position as private attorneys general").

Defendants attempt to transform Plaintiffs' allegations into a patent claim, taking rules for

standing to initiate a challenge under *patent law* and improperly import those standards into *antitrust* standing analysis. Petition 19-21. But this conceives of *Walker Process* as a kind of patent claim: the very error which the Seventh Circuit made – and the Supreme Court reversed – in *Walker Process*.[33] And "*Walker Process* itself, of course, reflects a willingness to let antitrust liability impact the patent system." App. 22a. As Amici concede, a *Walker Process* theory "arises under [the] antitrust laws[.]" BIO Brief at 15. Therefore, the Second Circuit here properly refused to strip Plaintiffs of standing, for fear of "creating the potential 'to leave a significant antitrust violation undetected or unremedied.'" App. 23a (*quoting Associated General Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 542 (1983)).

Defendants claim that the Second Circuit's decision on standing – again, an aspect of the decision on which Defendants have not sought certiorari on – may "chill" patent rights (Petition 20). But the law condemns, rather than protects, conduct like Defendants'. "Patents obtained by fraud and used to maintain a monopoly [] undermine both the

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[33] *See Food Mach. & Chem. Corp. v. Walker Process Equip., Inc.*, 335 F.2d 315, 316 (7th Cir. 1964), *rev'd*, 382 U.S. 172 (1965). The Seventh Circuit had affirmed dismissal of the antitrust claims reasoning that the suit sought the cancellation of a patent, and standing to seek such relief was then restricted to the U.S. government. This Court reversed.

patent system and the 'important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.'" Brief for the United States and Federal Trade Commission as *Amici Curiae* Supporting Plaintiffs-Appellants at 15, *In re DDAVP Direct Purchaser Antitrust Litig.*, Appeal No. 06-5525 (2d Cir.), filed May 25, 2007 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

Nor can Defendants invoke an "interest in protecting patentees... to frustrate the assertion of rights conferred by the antitrust laws." App. 23a (quoting *Walker Process*, 382 U.S. at 176). Having wrongly delayed generic competition, Defendants should be held answerable like any other antitrust defendant, and not win special rights to be heard in their preferred forum.

CONCLUSION

For these reasons, the Petition for Certiorari should be denied.

Respectfully submitted,

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May 28, 2010

APPENDIX

APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT FILED NOVEMBER 7, 2007

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of November, two thousand seven,

Present:

Hon. Roger J. Miner,
Hon. Rosemary S. Pooler,
Circuit Judges.[1]

05-2851-cv (L)
05-2852-cv (CON)
05-2863-cv (CON)

In re Ciprofloxacin Hydrochloride Antitrust Litigation.

Defendants-Appellees move to transfer to the United States Court of Appeals for the Federal Circuit these

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1. The Honorable Thomas J. Meskill, who was originally assigned to the panel, died before oral argument. The remaining two members of the panel, who are in agreement, decide this case in accordance with Second Circuit Local Rule 0.14(b).

three appeals. Upon due consideration, it is hereby ORDERED that the motion is GRANTED as to the appeal docketed under 05-2863-cv, which is TRANSFERRED to the Federal Circuit because the *Walker Process* claim in that case arises out of patent law. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988) (finding that a case "arises under" federal patent law if "a well-pleaded complaint establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims").

However, the motion is DENIED as to the appeals docketed under 05-2851-cv and 05-2852-cv because the claims therein rely on several theories, including alternative theories that do not require the determination of any substantial question of patent law. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2006) (finding that "even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction under 28 U.S.C. § 1338"); *see also Christianson*, 486 U.S. at 809 (finding that a case raising a patent law defense will not, for that reason alone, be said to "arise under" patent law, "even if the defense is anticipated in the complaint").

Thus, the appeal docketed under 05-2863-cv is transferred to the Federal Circuit, while the appeals docketed under 05-2851-cv and 05-2852-cv will remain consolidated in this Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

By: s/ Lucille Carr